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MAR 1 4 2005

510(k) SUMMARY

NAME OF FIRM:	DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, IN 46580
510(K) CONTACT:	Natalie S. Heck Manager, Regulatory Affairs DePuy Orthopaedics, Inc. PO Box 988 700 Orthopaedic Drive Warsaw, IN 46581-0988
TRADE NAME:	DePuy Pinnacle® Constrained Acetabular Liners
COMMON NAME:	Acetabular Cup Liner
CLASSIFICATION:	Class II, per 21 CFR, 888.3310 Hip joint metal/polymer/ metal, constrained, cemented or uncemented prosthesis
DEVICE PRODUCT CODE:	87 KWZ
SUBSTANTIALLY EQUIVALENT DEVICES:	**Biomet** RingLoc II Constrained Liners **Biomet** Freedom Constrained Liners **DePuy** SROM® Poly-Dial Acetabular Cup System Constrained Liners **DePuy** Duraloc® Acetabular Cup System Constrained Liners

DEVICE DESCRIPTION:

The Pinnacle® Constrained Acetabular Liner is part of a modular system designed to replace the natural articular surface of the hip joint in total hip replacement. The liner is manufactured from ultra high molecular weight polyethylene (UHMWPE), which locks into a porous coated, hemispherical outer shell component manufactured from titanium alloy (Ti-6Al-4V). The liner component articulates with a metal femoral head of an appropriate diameter.

The Pinnacle® Constrained Liner mechanically constrains the femoral head within the ID of the liner by providing greater than 180 degrees femoral head capture combined with a titanium constraining ring which fits over the opening diameter of the liner. The UHMWPE liner is held in the metal shell by means of a titanium locking ring.

The subject Pinnacle® Constrained Liners are UHMWPE acetabular cup liners that are available in a lateralized neutral or lateralized face-changing orientation. The liners have inner diameters (ID)

intended for use with modular femoral heads within the 28mm-36mm size range. The outer diameters (OD) are geometrically the same as other Pinnacle Acetabular Liners, in a 48mm-60mm size range offering.

INDICATIONS AND INTENDED USE:

Indications:

The Pinnacle® Constrained Polyethylene Liner is indicated for use as a component of a total hip prosthesis in primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease or intraoperative instability.

The Pinnacle® Constrained Liner is indicated for use with the Pinnacle® Acetabular Cup in cementless application.

Intended Use:

The subject Constrained Liner is intended to be used with the DePuy Pinnacle® metal acetabular shells, and modular femoral heads to resurface the acetabular socket in cementless total hip arthroplasty.

Basis of Substantial Equivalence:

The DePuy Pinnacle® Constrained Polyethylene Liner (lateralized neutral and lateralized face-changing), described in this submission is substantially equivalent to the predicate devices based on similarities in design, intended use, material and manufacturing methods. The design, while not identical to the predicates, does not raise any new issues of safety or effectiveness.

DePuy believes that the DePuy Pinnacle® Constrained liner is substantially equivalent to the previously cleared and approved devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 4 2005

Ms. Natalie S. Heck
Manager, Regulatory Affairs
Depuy Orthopedics, Inc.
P.O. Box 988
700 Orthopedic Drive
Warsaw, Indiana 46581

Re: K043058
Trade/Device Name: Pinnacle® Constrained Acetabular Liners
Regulation Number: 21 CFR 888.3310
Regulation Name: Hip joint metal/polymer constrained cemented or uncemented prosthesis
Regulatory Class: II
Product Code: KWZ
Dated: February 14, 2005
Received: February 16, 2005

Dear Ms. Heck:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Miriam Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K043058

Device Name: Pinnacle® Constrained Acetabular Liner

Indications for Use:

The Pinnacle® Constrained Acetabular Liner is indicated for use as a component of a total hip prosthesis in primary or revision patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease or intraoperative instability.

The Pinnacle® Constrained Acetabular Liner is indicated for use with the Pinnacle® Acetabular Cup in cementless application.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __No__ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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(Posted November 13, 2003)